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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,077	02/03/2004	Erik M. Erbe	OVIT-0283	1963

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,077	ERBE ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-43,63-71 and 73-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-43,63-71 and 73-78* is/are rejected.

7)☒ Claim(s) *67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Applicant's Request for Continued Examination filed 7 December 2005 has been received and entered into the case. Claims 1-31, 44-62, and 72 have been cancelled. Amendments to claim 63 has been entered. Claims 32-43, 63-71 and 73-78 remain pending, all of which have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim 67 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The amendment to claim 63 replaced the term 'polymer' with 'collagen' therefore the limitation in claim 67 that the polymer be collagen fails to further limit the parent claim; it appears claim 67 should be cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 recites the limitation "the polymer" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 68 recites the limitation "the polymer" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim, it appears the term should be replaced with 'collagen,' per the amendment to claim 63.

Claim 69 recites the limitation "the polymer" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim, it appears the term should be replaced with 'collagen,' per the amendment to claim 63.

The rejection of claims 71 and 73-78 under 35 USC § 112, second paragraph, have been withdrawn in view of applicant's arguments pointing to the specific definition of "homogenous" provided in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The amendment to claim 63 has obviated the rejection under 35 USC § 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-40, 63 and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piez et al (US Patent 4,795,467), in light of Bachand, in view of Sapiesko et al (US Patent 6,383,519) and further in view of Erbe et al (US 2002/0127720 A1).

Piez et al teach bone graft material comprised of a calcium phosphate mineral preparations and collagen (which applicant calls a biocompatible, resorbable polymer), wherein the collagen coats the pores of a porous calcium phosphate mineral block (See Piez et al, col. 2, ln 32-52). Piez et al teach the combination of calcium phosphate mineral and collagen provide a successful support for in-growth of new bone tissue. Piez et al teach the calcium phosphate mineral component can include a variety of forms of calcium phosphate, including SYNTHOGRAFT. SYNTHOGRAFT is a commercially available form of beta tricalcium phosphate; therefore the bone grafts of Piez et al can comprise calcium phosphate in the form of β tricalcium phosphate (See Piez et al col. 2, ln 59-68 & Bachand, Pg. 2). Piez et al teach the form of collagen is critical to the success of the implant; Piez et al use reconstituted fibrillar atelopeptide collagen (See Piez et al, col. 2, ln 38-39). The collagen is preferably obtained from the same individual to whom the graft is intended or from bovine sources, in order to reduce immune responses and increase biocompatibility (See Piez et al, col. 1, ln 30-35). Piez et al also teach bone marrow, blood and saline can also be applied to the graft material (See Piez et al, col. 5, ln 15-21) (Claim 39).

Piez et al teach the bone graft material can be prepared by mixing the two components together into a cohesive mass and then loading the mixture into an appropriate container to provide a 'wet' product, or the mixture can be case into desired shapes, including blocks, squares, and sheets, then lyophilized to provide 'dry' product (See Piez et al, col. 4, ln 67- col. 4, ln 2). Alternatively, porous mineral blocks can be first formed by compacting the calcium phosphate minerals in the presence of liquid, then drying to form the porous block which can then be coated with the collagen (See Piez et al, col. 5, ln 36-42). Still further, the mineral particles of desired mesh can be loaded into a container and the collagen dispersion can be injected into the container to provide collagen coated pores (See Piez et al, col.

5, ln 44- col. 6, ln 4). However, Piez et al does not teach how such methods would allow for controlled porosity in the final graft material.

However, at the time the invention was made Sapiesko et al had developed a method for producing inorganic shaped bodies that simultaneously demonstrated macro-, meso-, and microporosity (See Sapiesko et al, col. 4, ln 1-65). The inorganic shaped bodies of Sapiesko et al preferably comprise β tri-calcium phosphate (See Sapiesko et al, col. 8, ln 38-46) and can be used in the formation of bone grafts (See Sapiesko et al, col. 5, ln 7-47). The inorganic shaped bodies of Sapiesko et al can further be reinforced by coating with polymers (See Sapiesko et al, col. 4, ln 31-34). The shaped bodies can be formed into a variety of shapes, including blocks, disks, cylinders, or sleeves for orthopedic surgery (See Sapiesko et al, col. 12, ln 1-13; col. 23, ln 63-65; col. 42, ln 64-67).

Therefore, it would have been obvious to one of ordinary skill in the art to alternatively use the β tri-calcium phosphate shaped bodies of Sapiesko et al as the calcium phosphate mineral component in the graft of Piez et al; such shaped bodies would be coated with the reconstituted fibrillar atelopeptide collagen as taught in Piez et al to produce bone grafts with macro-, meso-, and microporosity (Claims 32, 40, 63, and 67). One of ordinary skill in the art would have been motivated to use the β tri-calcium phosphate shaped bodies of Sapiesko et al as the calcium phosphate component in the graft of Piez et al because the β tri-calcium phosphate shaped bodies of Sapiesko et al have macro-, meso-, and microporosity (See Sapiesko et al, col. 4, ln 1-65). Such varied porosity is desirable in a bone graft material because it permits more thorough infiltration of therapeutics (such as the blood, saline or bone marrow aspirate), a more continuous supply of nutrients, more extensive cellular and tissue ingrowth into the scaffold, and enhanced revascularization, allowing bone growth and repair to take place more efficiently (See Erbe et al, Pg. 3, paragraph 0033). One would have expected success using the β tri-calcium phosphate shaped bodies of Sapiesko et al as the calcium phosphate mineral component in the graft of Piez et al because the shaped bodies of Sapiesko et al have the same chemical composition as

those created by Piez et al, they just have superior porosity; also Sapiesko et al teach their shaped bodies are suitable for coating with polymers and for use as bone grafting materials (See Sapiesko et la, col. 4, ln 31-34 & col. 4, ln 7-57).

Regarding the shape of the bone graft, Sapiesko et al teach the shaped organic bodies can be formed into a variety of shapes, including blocks, disks, cylinders, or sleeves for orthopedic surgery (See Sapiesko et al, col. 12, ln 1-13; col. 23, ln 63-65; col. 42, ln 64-67); however, it would have further been obvious to one of ordinary skill in the art at the time the invention was made to form the graft into any desired shape, including a sleeve shape or a half sleeve shape, wherein the cross section of the sleeve is in the shape of a crescent moon, semi-sphere, semi-tubular, torus, or in a shape to conform to the acetabulum or any other desired anatomical tissue structure (Claim 70). One of ordinary skill in the art would have been motivated to form the β tricalcium phosphate shaped body of Sapiesko et al into any desired shape for the use as the bone graft material of Piez et al, including those listed above, in order to better fit the bone graft to the osseous void it will be engrafted to. For example, a semi-sphere shaped graft would be more desirable for replacing or repairing a rotator cup on a shoulder than a flat disk. One would have expected success forming the bone graft of Piez et al into any desired shape because the shape of the graft relies on the shape of the mineral component, and Sapiesko et al teach their shaped bodies can be formed in any desired shape by preshaping the sponge or material into the desired form.

Regarding the ratio of the calcium phosphate to collagen in the graft, Piez et al teach the bone graft composition should comprise approximately 75-98% by weight calcium phosphate mineral component and approximately 25-2% by weight collagen (See Piez et al, col. 4, ln 57-65) (mass ratio of beta-tricalcium phosphate and collagen is (75-98):(25-2); therefore the mass ratio can be 70:30, 80:20 or 90:10) (Claims 34-38, 68 & 69). In using the inorganic shaped body of Sapiesko et al as the β tricalcium phosphate mineral component of the bone graft one of ordinary skill in the art would be able to manipulate the pore volume of the shaped body to achieve the desired ratio of calcium phosphate and

collagen. The amount of collagen present in the graft material is directly related to the total pore volume of the porous mineral component. Sapiesko et al teach the shaped bodies can be formed so as to have pore volumes ranging from 30% up to over 90%; Sapiesko et al teach the pore volume can be controlled for (See Sapiesko et al, col. 4, ln 54-65). One of ordinary skill in the art would have been motivated to manipulate the pore volume of the β tricalcium phosphate shaped body in order to increase or decrease the ratio of calcium phosphate to collagen in order to alter the rigidity of the graft material, within the range of about 75-98% by weight calcium phosphate mineral component and about 25-2% by weight collagen, as taught by Piez et al. For example, one of ordinary skill in the art would desire a high calcium phosphate to collagen ratio in order to produce a more rigid graft material, for graft use in long bones or other load bearing bone grafts. A lower calcium phosphate to collagen ratio would be desirable in grafts where load bearing capabilities are not immediately necessary, for instance cranial grafts do not need to be able to withstand the weight of the body, rather a higher amount of resorbable collagen would be tolerable, then the resorbable collagen would eventually be replaced with a greater number of natural bone cells. One would have expected success because Sapiesko et al teach that the pore volume can be controlled for, therefore it would be a matter of routine optimization to manipulate the pore volume to produce the desired ratio of calcium phosphate to collagen, as desired for the intended use of the graft material.

Finally, regarding the type of collagen, though Piez et al teaches the collagen can come from a bovine source, they do not teach a specific type of bovine collagen. However, they do teach that purified atelopeptide fibrillar reconstituted collagen is suitable for their bone graft material (See Piez et al, col. 4, ln 41-42). Piez et al also teach type I collagen, derived from bones, is the most common type of collagen, and they teach a method to remove the telopeptides from common collagen to produce "atelopeptides." (See Piez et al, col. 3, ln 17-col. 4, ln 15). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use fibrillar type I bovine collagen in the bone graft

material of Piez et al because Piez et al teach bovine collagen has low immune response when used in humans, they teach type I collagen is the most common type of collagen, easily found in bone sources, and Piez et al teach a method using proteolytic enzymes to remove the telopeptides from type I collagen to produce the desired "atelopeptide" collagen used in their material (Claim 33). One of ordinary skill in the art would have been motivated to use type I bovine collagen as the collagen source because Piez et al teach that bovine collagen has low immune response when used in humans, and they teach that type I collagen, derived from bones, is the most common type of collagen; therefore type I bovine collagen would be easy to obtain. One would have expected success because Piez et al teach that atelopeptide fibrillar collagen is suitable for use in the bone graft material, and they provide a method to remove the telopeptides.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 32, 34-43, 63-71 and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piez et al (US Patent 4,795,467), in light of Bachand, in view of Sapiesko et al (US Patent 6,383,519), Erbe et al (US 2002/0127720 A1), Koblish et al (US Patent 6,458,162), Lin et al (US Patent 6,458,162) and Sanders et al (US Patent 5,290,289).

Piez et al teach bone graft material comprised of a calcium phosphate mineral preparations and collagen (which applicant calls a biocompatible, resorbable polymer), wherein the collagen coats the pores of a porous calcium phosphate mineral block (See Piez et al, col. 2, ln 32-52). Piez et al teach the calcium phosphate mineral component can include a variety of forms of calcium phosphate, including SYNTHOGRAFT. SYNTHOGRAFT is a commercially available form of beta tricalcium phosphate; therefore the bone grafts of Piez et al can comprise calcium phosphate in the form of β tricalcium phosphate (See Piez et al col. 2, ln 59-68 & Bachand, Pg. 2). Piez et al teach the form of collagen is

critical to the success of the implant; Piez et al use reconstituted fibrillar atelopeptide collagen (See Piez et al, col. 2, ln 38-39). Piez et al also teach bone marrow, blood and saline can also be applied to the graft material (See Piez et al, col. 5, ln 15-21) (Claim 39).

While Piez et al does not teach using calcium phosphate mineral blocks that necessarily have macro-, meso-, and microporosity, at the time the invention was made it would have been obvious to one of ordinary skill in the art to alternatively use the β tri-calcium phosphate shaped bodies of Sapiesko et al as the calcium phosphate mineral component in the graft of Piez et al; such shaped bodies would be coated with the reconstituted fibrillar atelopeptide collagen as taught in Piez et al to produce bone grafts with macro-, meso-, and microporosity (Claims 32, 40, 63, and 67). See teachings above.

Regarding the shape of the bone graft, Sapiesko et al teach the shaped organic bodies can be formed into a variety of shapes, including blocks, disks, cylinders, or sleeves for orthopedic surgery (See Sapiesko et al, col. 12, ln 1-13; col. 23, ln 63-65; col. 42, ln 64-67); however, it would have further been obvious to one of ordinary skill in the art at the time the invention was made to form the graft into any desired shape, including a sleeve shape or a half sleeve shape, wherein the cross section of the sleeve is in the shape of a crescent moon, semi-sphere, semi-tubular, torus, or in a shape to conform to the acetabulum or any other desired anatomical tissue structure (Claim 70). See teachings above.

Regarding the ratio of the calcium phosphate to collagen in the graft, Piez et al teach the bone graft composition should comprise approximately 75-98% by weight calcium phosphate mineral component and approximately 25-2% by weight collagen (See Piez et al, col. 4, ln 57-65) (mass ratio of beta-tricalcium phosphate and collagen is (75-98):(25-2); therefore the mass ratio can be 75:25, 80:20 or 90:10) (Claims 34-38, 68 & 69). In using the inorganic shaped body of Sapiesko et al as the β tricalcium phosphate mineral component of the bone graft one of ordinary skill in the art would be able to manipulate the pore volume of the shaped body to achieve the desired ratio of calcium phosphate and collagen. See teachings above.

Neither Piez et al or Sapiesko et al teach or suggest including a metal or polymer mesh or plate in the graft material.

However, at the time the invention was made it was known in the art to incorporate metal and/or polymer materials in bone grafts in order to provide support and increase structural integrity of the graft. For example, Koblish et al teach a similar bone graft material comprising porous calcium phosphate that can be formed on, around, or immersed within a solid material, such as metal or polymers (See Koblish et al, col. 26, ln 56-col. 27, ln 57). The metals and/or polymer material provides support and increased structural integrity, especially in load-bearing grafts, such as in the spinal vertebrae. Koblish et al teach suitable metals for such grafts include stainless steel, titanium, silver, gold and other metals stable in the human body (See Koblish et al, col. 27, ln 1-3). Furthermore, though Koblish et al describe a solid metal and/or polymer material, it would have been obvious to one of ordinary skill in the art to alternatively use a metal and/or polymer in mesh form. One of ordinary skill in the art would have been motivated to use a mesh material in order to allow for less restricted flow of biological materials, such as osteocytes and blood flow into and out of the graft. One would have expected success because a strong mesh would provide similar support as solid material, and one of ordinary skill in the art would know how to perform such substitution.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate metal and/or polymer mesh or plate components into the bone graft of Piez et al, created with the shaped body of Sapiesko et al, in order to improve structural stability and provide additional support to the bone graft of Piez et al (Claims 41, 42, 64-66, 71, and 73-78). The skilled artisan would have been motivated to add a metal or polymer mesh or plate component to the bone graft of Piez et al, created with the shaped body of Sapiesko et al, in order to provides support during development of the bone graft, and to provide increased stability and structural integrity to the bone graft after implantation. One would have been motivated to immerse the metal or polymer mesh or plate

within the bone graft of Piez et al, created with the shaped body of Sapiesko et al, when the bone graft is large in size, for example, in long bone grafts. Similarly, one would have been motivated to affix the mesh to the surface of a sleeve shaped graft in order to maintain structural integrity once implanted. One would have expected success applying a metal or polymer plate or mesh, such as those taught or suggested by Koblish et al, to the grafts of Piez et al, created with the shaped body of Sapiesko et al, because Koblish et al teach successfully incorporating the metal and polymer materials into similar bone grafts; therefore one would expect similar success performing the same incorporation of the metal or polymer grafts into the grafts of Piez et al, created with the shaped body of Sapiesko et al.

Regarding the material of the metal or polymer mesh or plate material, while Koblish et al teach use of stainless steel, titanium, silver, and gold, they do suggest use of other metals that are stable in the human body (See Koblish et al, col. 27, ln 1-3). Therefore, at the time the invention was made it would have been well within the purview of one of ordinary skill in the art to use other metals and polymers which were known to be stable in the human body, such as nitinol and polyetheretherketone (PEEK) (Claims 66 and 73). At the time the invention was made nitinol was known to be suitable for use in the human body, for example, Sanders et al teach that nitinol is especially suitable for implantation and has particular applicability in augmenting or restoring damaged spinal vertebrae that are misshaped, due to its ability to "remember" its designated shape (See Sanders et al, col. 4, ln 13-47). Additionally, at the time the invention was made PEEK was known to be suitable for use in the human body, for example, Lin et al teach PEEK to have excellent mechanical properties and machinability, and PEEK materials have been shown to be suitable for implantation (See Lin et al, col. 5, ln 38-52). Therefore, one of ordinary skill in the art would have been motivated to use nitinol or polyetheretherketone as the supporting material in the grafts of Koblish et al because based on the teachings of Sanders et al and Lin et al regarding the suitability and desirable qualities of the two materials for in vivo use. One would have expected success using either nitinol or PEEK as the mesh or plate materials in the graft of Piez et al because it was known

at the time the invention was made that metal plates or meshes were beneficial in bone grafts (See Koblish et al), and both nitinol and PEEK were known to be suitable for in vivo use (See Sanders et al and Lin et al).

Finally, it would have further been obvious to one of ordinary skill in the art at the time the invention was made to shred the graft material of Piez et al, created with the shaped body of Sapiesko et al (Claim 43). One would have been motivated to shred the graft material of Piez et al in order to fill a metal or polymer body housing, such as those described by Koblish et al, with the bone graft shreds. By shredding the bone graft material one can increase the pore volume of the graft, therefore allowing for increased pore volume for ingrowth of autogenous bone and blood cells. Filling a housing with shredded bone grafts provides a prosthesis with the appropriate bone graft material, but wherein the structural integrity comes exclusively from the housing. Shredding the bone graft material and depositing the shreds in a solid housing would be a desirable means to utilize pieces of left over bone graft materials that are not large enough to act as a complete, solid graft, but rather can be shredded and packed in housing. One would have expected success because shredding the bone graft material of Piez et al, created with the shaped body of Sapiesko et al, could be done by such simple methods as processing left over pieces in a blender.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 7 December 2005 have been fully considered; new grounds of rejection have been presented to better address the current invention. Applicants arguments focus on the lack of teachings or suggestion in Piez et al with respect to macro-, meso-, and microporosity of the graft materials. Applicants argue that Piez et al does not teach a graft material with macro-, meso-, and

microporosity, and that the examiner did not provide any additional references showing that one of ordinary skill in the art would be motivated to modify Piez et al in the manner set forth in the rejections. Applicants feel the examiner relied on impermissible hindsight to arrive at the conclusions.

In response new grounds of rejection have been set forth, wherein it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the bone graft material of Piez et al to comprise the β tricalcium phosphate shaped bodies taught by Sapiesko et al which exhibit macro-, meso-, and microporosity, as well as controllable pore volume. The motivation to use the β tricalcium phosphate shaped bodies of Sapiesko et al comes from the teachings of Erbe et al, which states varied porosity is desirable in a bone graft material because it permits more thorough infiltration of therapeutics, a more continuous supply of nutrients, more extensive cellular and tissue ingrowth into the scaffold, and enhanced revascularization, allowing bone growth and repair to take place more efficiently (See Erbe et al, Pg. 3, paragraph 0033). Motivation has been directly provided in the prior art, therefore no impermissible hindsight has been relied upon to arrive at the present grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER